

Factual and Procedural Background

Plaintiff Alzheimer's Institute of America, Inc. ("AIA") brought this action for patent infringement against defendants Avid Radiopharmaceuticals ("Avid") and The Trustees of the University of Pennsylvania ("Penn"). After conducting discovery, AIA and Avid have filed cross-motions for summary judgment on the issue of whether AIA has standing to prosecute this action. Penn has joined in Avid's motion.

The patents in suit are for technology related to Alzheimer's disease, including nucleic acids coding for the so-called "Swedish mutation" and transgenic mice carrying the mutation. Alzheimer's disease is the result of neuronal death believed to be caused by aggregations in the brain of plaques formed by a peptide known as beta-amyloid, which is released from a larger protein known as the amyloid precursor protein ("APP"). A mutation in the APP gene, known as the Swedish mutation, is believed to be the cause of the release of beta-amyloid plaques leading to Alzheimer's disease.

Dr. John A. Hardy, who Avid claims is a co-inventor of the Swedish mutation, headed a research laboratory team at St. Mary's Hospital Medical School ("St. Mary's") in London searching for a genetic cause of Alzheimer's disease.¹ Hardy began at St. Mary's in 1984.² Among the members of the St. Mary's research team were doctoral candidates Michael Mullan, who AIA contends is the sole inventor, and Fiona Crawford. St. Mary's merged with Imperial College ("Imperial") in 1988. Mullan joined Imperial as a Clinical

¹ AIA's Statement of Undisputed Facts ("SOF") ¶ 29.

² Declaration of Dr. John A. Hardy, Apr. 29, 2011 ("Hardy Decl.") ¶ 5.

Research Fellow on October 1, 1988 and received his Ph.D. in December 1993.³

In a 1990 paper, co-authored with scientists from the Netherlands, Hardy described a linkage between the APP gene and a disease called “hereditary cerebral hemorrhage with amyloidosis of the Dutch type” (“HCHWA-D”), which is also linked to amyloid deposits. The paper concluded that a mutation in the APP gene, known as the “Dutch mutation,” was responsible for HCHWA-D.⁴

After the discovery of the Dutch mutation, Hardy’s team began to search for APP mutations related to Alzheimer’s by sequencing part of the APP gene known as exon 17 taken from a small British family. Exon 17 was selected because it was one of two exons encoding the beta-amyloid peptide and was the location of the Dutch mutation.⁵ As a result of the team’s research, it discovered a mutation, now known as the “London mutation,” at codon 717 of the APP gene. The team associated the mutation with early-onset Alzheimer’s disease.⁶

The St. Mary’s team, then under the auspices of Imperial College, filed a United Kingdom patent application for the London mutation. The application named Hardy, Mullan and three other team members as the inventors. The team members suggested patenting transgenic animals carrying the mutation. Imperial’s technology transfer arm, Imperial Exploitation Limited (“IMPEL”), erroneously advised them that transgenic animals could not

³ AIA’s SOF ¶¶ 24, 28, 30; Avid’s response to AIA’s SOF ¶ 114. Mullan’s appointment was initially set to expire on September 30, 1990, but it was extended on several occasions and lasted at least until December 1, 1991. *Id.* ¶¶ 24-27.

⁴ Hardy Decl. ¶ 6.

⁵ Hardy Decl. ¶¶ 8-9; Avid’s Mot. for Summ. J. (Doc. No. 63) at 4.

⁶ AIA’s SOF ¶ 36.

be patented under U.K. law.⁷

In February 1991, after the initial patent application was filed, Athena Neurosciences, Inc. ("Athena") of San Francisco approached Imperial, through Hardy, to sponsor the team's research to identify new APP mutations. On August 1, 1991, a Sponsored Research Agreement was executed. Athena then redrafted the patent application to include transgenic animals carrying the London mutation. The agreement granted Athena exclusive rights to mutation-carrying transgenic animals and to any subsequent Alzheimer's discoveries from the laboratory. Upon learning that IMPEL had given them erroneous advice, the research team was disappointed with the deal they had made with Athena.⁸

In 1990, Kansas City businessman Ronald Sexton arrived on the scene.⁹ According to Avid, after discussions with Sexton, Hardy and Mullan contacted Imperial to attempt to renegotiate Imperial's claim to the patent. Imperial categorically rejected their request, citing the U.K. Patents Act 1977 for the principle that inventions made in the normal course of employment duties belong to the employer, not to the employee.

Shortly after Imperial's rejection, Hardy and Mullan decided to conduct further research in Florida.¹⁰ They accepted an offer from the University of South Florida ("USF") to set up a new laboratory dedicated to Alzheimer's research. It is undisputed that, by the

⁷ Hardy Decl. ¶ 9.

⁸ Hardy Decl., ¶¶ 10-13; Transcript of oral argument, Aug. 10, 2011 at 24.

⁹ Deposition of Michael Mullan, Mar. 1, 2011 at 195-96; Hardy Decl. ¶ 14.

¹⁰ The parties disagree about the motivation for relocating the research to Florida. AIA claims that the reason was the "poor research funding environment in Britain." Avid contends it was to avoid the Athena agreement and the effect of U.K. law bestowing ownership rights on Imperial.

end of 1991, Mullan relocated to Florida and began setting up a laboratory with Hardy as its titular head. Mullan's appointment at USF began December 16, 1991.¹¹

Discovery of the London mutation spurred laboratories around the world to search their Alzheimer's patient samples for APP mutations. In January 1992, Dr. Lars Lannfelt, part of a research team led by Dr. Bengt Winblad at the Karolinska Institute in Sweden, began collecting DNA samples from Swedish families afflicted with Alzheimer's. In February 1992, Lannfelt visited Hardy's London laboratory and brought DNA samples from two Swedish families. Hardy then instructed Henry Houlden, a medical student, to analyze the DNA for linkage between Alzheimer's and a genetic marker known as GT12, which was known to reside near the APP gene on chromosome 21.¹² According to Avid, Hardy concluded that the data generated by Houlden's analysis indicated a strong likelihood of a mutation on the APP gene in both of the Swedish families.¹³

Avid contends that Hardy wanted to avoid any ownership claim by Imperial in the anticipated mutation discovery. Consequently, he sent the DNA samples from affected and unaffected Swedish family members to Mullan to do sequencing in Florida rather than in Imperial's London laboratory.

Upon receiving the samples, Mullan used a computer program on Houlden's data to generate "logarithm of the odds" ("LOD") scores. Avid contends that the resultant scores were consistent with Hardy's conclusion that there was a strong likelihood of a mutation on the APP gene. Without informing Hardy, Mullan instructed Crawford to conduct DNA

¹¹ AIA's SOF ¶¶ 41, 43-44, 47.

¹² AIA's SOF ¶¶ 50, 53-54.

¹³ Hardy Decl. ¶ 28.

sequencing at an off-campus laboratory at the Tampa Bay Research Institute ("TBRI") instead of in the USF laboratory.¹⁴

Sequencing results for exon 16, the other exon encoding the beta-amyloid peptide, revealed a double mutation at codons 670 and 671, now known as the Swedish mutation. Several days later, when Mullan informed Hardy of the mutation, the two agreed that Hardy's name would not be included on any publication related to the Swedish mutation.¹⁵

Mullan and Hardy, along with Sexton, then sought USF's waiver of any rights it may have in the Swedish mutation. They hired a U.K. law firm, Clyde & Co., to send a letter to USF asking that ownership of rights to any "inventions made by them (whether before or after the date of the letter) belong exclusively to Hardy and Mullan." The letter made no specific mention of the recent discovery of the Swedish mutation while Mullan was employed by USF. The letter was signed on May 4, 1992 by George R. Newkome, Vice President for Research at USF. Newkome made one revision to the letter, changing the language "whether before or after the date of this letter" to "before August 15, 1992."¹⁶

Avid contends that USF believed that the Swedish mutation work had been substantially completed prior to Mullan's employment there.¹⁷ According to Avid, only later did USF learn that the discovery was the result of work done in Florida. The record is

¹⁴ AIA's SOF ¶¶ 61; Hardy Decl. ¶ 32.

¹⁵ AIA's SOF ¶¶ 72, 78. Avid alleges that Hardy's name was excluded to avoid the Imperial-Athena agreement. AIA contends that it was excluded because Hardy's contributions were not significant enough to constitute inventorship.

¹⁶ See Ex. 5 to Avid's Mot. for Summ. J. (Doc. No. 63). Newkome's initials appear in the margin where the change was made.

¹⁷ See Ex. 6 to Avid's Mot. for Summ. J. (Doc. No. 63). If the research had been substantially done before Mullan did the sequencing, Hardy's contention that he was a co-inventor gains traction.

unclear about what USF knew about the work on the Swedish mutation at the time the purported waiver letter was presented.

On May 5, 1992, the day after Newkome countersigned the Clyde & Co. letter, Sexton incorporated AIA as a Florida for-profit corporation for the purpose of holding and exploiting the rights to the Swedish mutation. AIA's first annual report, issued in 1993, listed Sexton as president, and Mullan as vice president and treasurer.¹⁸

The patent application for the Swedish mutation was filed one month later, on June 4, 1992. It named Mullan as the sole inventor. On July 15, 1992, Mullan executed an assignment to AIA of his rights in the invention, including any patents or continuations. The assignment was recorded in the U.S. Patent and Trademark Office ("PTO") on July 31, 1992.¹⁹

Mullan and Crawford were awarded doctorate degrees from Imperial in 1993 and 1994, respectively, according to Avid, in large part due to their work on the Swedish mutation. At the time of discovery of the Swedish mutation, an Imperial College regulation imposed upon Imperial students an obligation to disclose and assign their inventions to Imperial. There is no evidence that they did so. Mullan claims that he was not an Imperial student in 1992 while working on his dissertation.

On October 3, 1995, the first of the patents in suit issued from the June 4, 1992 application as U.S. Patent No. 5,455,169 ("the '169 patent") for a nucleic acid encoding an APP protein carrying the Swedish mutation, along with vectors comprising the nucleic acid and cell lines containing the nucleic acid. On March 8, 2007, Mullan filed a continuation

¹⁸ AIA's SOF ¶ 1. Hardy's interest in AIA is unclear from the parties' briefs. At oral argument, AIA's counsel represented he had none.

¹⁹ AIA's SOF ¶¶ 2, 4, 6.

application, again naming himself as the sole inventor. On May 26, 2009, the continuation application issued as U.S. Patent No. 7,538,258 ("the '258 patent") for transgenic mice carrying the nucleic acid and for screening methods for an agent for treating Alzheimer's using such mice. The '258 patent was assigned to AIA pursuant to the original assignment.²⁰

On November 24, 2010, AIA brought this action alleging patent infringement by defendants Avid and Penn. After conducting a Rule 16 conference, we ordered the parties to conduct discovery limited to the issue of whether AIA has standing to bring this action. Pursuant to the scheduling order, Avid conducted discovery and filed a motion seeking summary judgment that AIA lacks standing, contending that Mullan was not the sole inventor; and if he was, the rights to the Swedish mutation inventions vested in USF as a condition of Mullan's employment pursuant to Florida law. According to Avid, the purported waiver on the part of USF was ineffective because it did not comply with the regulations and was not knowingly made. In the alternative, Avid argues that Imperial owned the rights to the inventions because Mullan was a student and employee of Imperial when the inventions were conceived. Avid asserts that in either case Mullan owned no rights to the inventions and, thus, had no rights to assign to AIA. Therefore, so Avid argues, AIA has no standing to bring a patent infringement action for the patents in suit.

AIA filed a cross-motion for summary judgment on the standing issue, arguing that the patents listing it as owner are entitled to a presumption of validity. According to AIA, Mullan is the sole inventor; and, although involved in research resulting in the inventions, none of the other individuals made a contribution sufficient to rise to the level of

²⁰ AIA's SOF ¶¶ 4, 7-8, 10.

inventorship. AIA further contends that USF has no rights in the patents because Mullan was not bound by the Florida regulation; he did not agree to be bound by the regulation's terms; and even if the regulation vested rights in USF, USF waived them in favor of Mullan. Similarly, according to AIA, Imperial has no rights in the patents because Mullan was not acting as an employee or as a student of Imperial when the inventions were conceived.

There are disputed material facts precluding summary judgment on the inventorship issue. On the ownership issue, we conclude that Mullan was subject to a Florida regulation vesting ownership in USF of the inventions he made during the course of his employment there. Consequently, unless USF waived its right to the inventions, he had no rights to assign to AIA. Thus, absent a valid waiver, AIA lacks standing to bring this action.

Discussion

Standing is a threshold issue on which the plaintiff bears the same burden of proof and evidentiary standard as at trial. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). To have standing to assert patent infringement under 35 U.S.C. § 271, AIA must demonstrate that it held enforceable title to the patent at the inception of the lawsuit. *Paradise Creations, Inc. v. UV Sales, Inc.*, 315 F.3d 1304, 1309 (Fed. Cir. 2003).

Inventorship

On the inventorship issue, AIA argues that Hardy and others did not make any significant contributions to the inventions. According to AIA, Hardy's participation was limited to developing a research plan and giving instructions to Houlden and Crawford, who make no claim to co-inventorship and merely carried out routine chores as directed by Mullan.

Not surprisingly, Avid contends Hardy played a much more significant role in the

conception of the inventions. It claims Hardy and Mullan were collaborating all along in the research that led to the discovery of the Swedish mutation. Despite Hardy's early disclaimers, he now insists that he was a co-inventor. At the time Mullan joined USF and later Hardy, the research that ultimately led to the conception of the invention was a work in progress. What each did and the extent of this contribution to the end result is disputed and presents a jury issue.

The inventor named on a patent is presumed to be the only inventor. *Acromed Corp. v. Sofamor Danek Group, Inc.*, 253 F.3d 1371, 1379 (Fed. Cir. 2001) (citations omitted). To rebut that presumption, the challenger must prove by clear and convincing evidence that someone else was the actual inventor or a joint inventor. *Id* (citations omitted). Additionally, a co-inventor need not contribute to every claim of a patent. *Ethicon, Inc. v. United States Surgical Corp.*, 135 F. 3d 1456, 1460 (Fed. Cir. 1998). A contribution to a single claim is sufficient. *Id*.

Because proving non-joinder of an actual inventor invalidates a patent, the self-serving testimony of the alleged joint inventor alone is insufficient to meet the clear and convincing evidence standard. *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F. 3d 1279, 1295 (Fed. Cir. 2008) (citing *Ethicon, Inc.*, 135 F.3d at 1461). There must be corroborating evidence. *Id*. Depending on the facts of the case, corroborating evidence can be found in documentary or physical evidence made contemporaneously with the inventive process, which is considered the most reliable; circumstantial evidence of an independent nature; or oral testimony from someone other than the alleged inventor or an interested party. *Checkpoint Sys., Inc. v. All-Tag Security S.A.*, 412 F.3d 1331, 1339 (Fed. Cir. 2005).

The proffered corroborating evidence is evaluated using a “rule of reason” analysis. *Lazare Kaplan Int’l, Inc. v. Photoscribe Technologies, Inc.*, 628 F.3d 1359, 1374 (Fed. Cir. 2010) (internal quotations and citations omitted). All pertinent evidence is examined to determine the alleged inventor’s credibility. *Id.*

AIA contends that it is the assignee of the patent pursuant to an assignment from the sole inventor. It argues that the patent is not invalid. As the moving party, AIA must demonstrate that Avid failed to produce clear and convincing evidence that Mullan, AIA’s assignor, was not the sole inventor. *Eli Lilly and Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 962 (Fed. Cir. 2001). Conversely, as the party moving to invalidate the patent, Avid must produce clear and convincing evidence that Mullan was not the sole inventor. *Id.*

Neither party has met its burden at this stage. Indeed, Avid concedes that there are disputed material facts that preclude summary judgment on the inventorship issue. AIA disagrees, arguing that Avid has not presented undisputed facts showing, by clear and convincing evidence, that Mullan was not the sole inventor. With respect to AIA’s motion, we must view the evidence in the light most favorable to Avid and resolve all doubts in its favor.

AIA argues that the only evidence Avid presented, Hardy’s testimony, was unreliable and uncorroborated. There is no question that Hardy has in the past denied that he was a co-inventor of the Swedish mutation. AIA contends that his current position to the contrary is not corroborated.

There is circumstantial evidence from which a reasonable jury could conclude that Mullan was not the sole inventor and that Hardy was a co-inventor. Hardy and Mullan both worked on the research to identify APP mutations. They started and continued down the

research path leading to the discovery of the Swedish mutation. Hardy sent the DNA samples to Mullan in Florida for the sequencing that identified the Swedish mutation. Hardy and Mullan were both employed at the USF laboratory at the relevant time. They both met with Sexton to finance the research.

The April 29, 1992 letter seeking a waiver authored by the solicitors representing Hardy and Mullan itself may be corroborating documentary evidence. Written to USF in anticipation of Hardy and Mullan working there, it references the work the two had done while at St. Mary's "in important developments in Alzheimer's disease." It sought recognition of their "ownership in work carried out by them and inventions made by them before August 13, 1992." Drawing inferences in favor of Avid, one could conclude from the letter that Hardy and Mullan jointly engaged in the research project that was a work in progress that resulted in the invention that was conceived before August 13, 1992. Thus, this letter is circumstantial documentary evidence that tends to corroborate Hardy's contention that he was a co-inventor.

Avid has proffered Houlden's declaration that supports its position that Hardy was a co-inventor. Houlden declares that he made contemporaneous notes regarding the work the members of Hardy's team did in the development of the Swedish mutation. He also explained that both Hardy and Mullan wanted the sequencing done in Florida to avoid any claim of ownership of the invention by St. Mary's.

Hardy's testimony together with the documentary and circumstantial evidence tending to corroborate it raises a jury question as to the who invented the Swedish mutation. Therefore, we cannot, in the face of the disputed facts, grant AIA's motion for summary judgment.

Ownership

The dispositive question is not who made the inventions but who owns them. Whether Mullan was the sole inventor or a co-inventor may be a disputed issue. But, there is no dispute that the inventions were conceived at the time that he was employed at USF; and Hardy, who claims to be a co-inventor, was employed by both Imperial and USF. The answer to the question of ownership lies in the efficacy of the Florida law governing ownership of inventions made by employees of USF during their employment. If the law applies, ownership of the inventions and, consequently, the patents vested in USF. In that case, Mullan would have had no interest to assign to AIA.

Under Florida law, inventions developed or discovered by an employee in the course of employment with USF are the property of USF. Fla. Admin. Code Ann. r. 6C4-10.012(3)(c), *implementing* Fla. Stat. § 240.229 (superseded by § 1004.23) (authorizing state universities to secure patents and enforce patent rights).²¹ USF employees are under

²¹ The Florida regulation provides, in pertinent part:

(3) Inventions.

(a) Disclosure/University Review.

1. An employee shall fully and completely disclose to the President or Vice President for Research all inventions which the employee may develop or discover while an employee of the State University System together with an outline of the project and the conditions under which it was done. . . .

(c) University-Supported Efforts. An invention which is made in the field or discipline in which the employee is employed by the University or by using University support is the property of the University and the employee shall share in the proceeds therefrom. . . .

(e) Release of Rights. . . .

2. At any stage of making the patent applications, or in the commercial application of an invention, if it has not otherwise assigned to a third party the right to pursue its interests, the President or Vice President for Research may elect to withdraw from further involvement in the protection or commercial application of the invention. At the request of the employee in such case, the University shall transfer the invention rights to the employee, in which case the invention shall be the employee's property

3. All assignments or releases of inventions, including patent rights, by the President or Vice President for Research to the employee shall contain the provision that such invention, if patented by the employee, shall be available royalty-free for governmental purposes of the State of Florida, unless otherwise agreed in writing by the University.

a duty to disclose to the University any inventions made during the course of their employment there. R. 6C4-10.012(3)(a)(1). The University reserves the right to relinquish its ownership interest. The regulation provides that an employee may seek the University's waiver of invention rights, provided that any assignment or release of rights contains a provision making the invention available royalty-free for governmental purposes to the State of Florida. R. 6C4-10.012(3)(e)(2)-(3).

Because Mullan was employed by USF when the inventions were conceived, ownership of the inventions vested in USF by operation of Florida law. "An invention which is made in the field or discipline in which the employee is employed by the University or by using University support is the property of the University and the employee shall share in the proceeds therefrom." R. 6C4-10.012(3)(c). Florida regulations promulgated pursuant to statutory authority have the force of law. *Menna v. Sun Country Homeowners Ass'n, Inc.*, 604 So. 2d 897, 899 n.1 (Fla. Dist. Ct. App. 1992) (citing *Fla. Livestock Bd. v. Gladden*, 76 So. 2d 291, 293 (Fla. 1954)); accord *Griffin v. Harris*, 571 F.2d 767, 772 (3d Cir. 1978) ("Validly promulgated regulations have the force and effect of law."). Therefore, under Florida law, although the inventor-employee has a right to share in the monetary benefits of the invention, ownership remains with the University-employer.

When an inventor's rights to an invention are deemed the property of his employer by operation of law, the inventor has no property rights to assign, and any purported assignee lacks standing to sue for patent infringement. See, e.g., *FilmTec Corp. v.*

(4) Execution of Documents. The University and the employee shall sign an agreement individually recognizing the terms of this rule.

(5) Responsibility. The authority and responsibility for administration and implementation of this rule is delegated to the Vice President for Research.

Hydranautics, 982 F.2d 1546, 1553-54 (Fed. Cir. 1992); *Cadence Design Sys., Inc. v. Bhandari*, No. 07-0823, 2007 WL 3343085, at *6 (N.D. Cal. Nov. 8, 2007) *Cf. Arachnid, Inc. v. Merit Indus., Inc.*, 939 F.2d 1574 (Fed. Cir. 1991) (holding a provision that rights “will be assigned” is an agreement to assign rather than a present transfer of rights, thus not nullifying plaintiff’s standing).

For ownership of the inventions to vest in USF, the evidence must demonstrate that Mullan was an employee of USF when the inventions related to the patents in suit were conceived and that the inventions were within the field or discipline of his employment. It is not necessary to prove that he used USF support. The invention need only have been in his field or discipline. The parties disagree when the inventions were conceived and reduced to practice. Avid contends this occurred in late March or early April of 1992. AIA claims that conception and reduction to practice were not complete until the original patent application was filed on June 4, 1992, the effective filing date for each patent.²² This is not a material dispute because whether the inventions were conceived and reduced to practice as early as March or as late as June of 1992, Mullan was an employee of USF.²³ As to the second element, it is undisputed that the inventions are within the field or discipline in which Mullan was employed by USF. Therefore, because Mullan was employed by USF when the inventions related to the patents in suit were conceived and the inventions were within the field in which Mullan was employed by USF, rights to the patents in suit vested

²² Avid’s SOF ¶ 2.

²³ Avid’s SOF ¶ 3; see also Avid’s ex. 21 at USF000050; AIA’s ex. 19 at USF000050.

immediately in USF by operation of the Florida regulation.²⁴

As a USF employee, although Mullan is entitled to share in the proceeds of the revenue from the inventions, he does not have ownership rights to them. He can assign his right to share in the proceeds. He cannot assign any right to ownership because he has none.

AIA argues that there was no transfer of rights to USF because there was no written assignment as required by 35 U.S.C. § 261. This argument fails for two reasons. First, the premise that there was a transfer is wrong. Mullan had no property to transfer. The ownership of the inventions vested immediately in USF. Second, even if it were considered a transfer of ownership from the inventor to the employer, assignment is not the only legal method of transfer. An ownership interest in a patent may pass from the inventor to another by operation of law.

Section 261 provides that an assignment of a patent is valid only if it is executed in writing and recorded with the PTO. AIA contends USF has no ownership interest in the inventions because there is no written assignment from Mullan. AIA relies on *University Patents, Inc. v. Kligman* for the assertion that § 261 is the only method for transfer of patent ownership interests. See 762 F. Supp. 1212, 1219 (E.D. Pa. 1991) ("Since a patent is a creature of federal statutory law, it may be transferred only in the manner provided by such law."). AIA misreads *Kligman*. *Kligman* instructs that ownership rights in the inventions are generally governed by state, not federal, law. *Id.* at 1219 n.8.

AIA's argument ignores that a § 261 assignment applies to patent rights, not to

²⁴ The Florida regulation's provision that employees' inventions are property of the University is a provision for an immediate, present transfer, in contrast to the provision in *Arachnid*, vesting the rights to the patents immediately in USF.

ownership rights, a distinction noted in *Kligman*. See *Kligman*, 762 F. Supp. at 1218-19 (acknowledging that patents and patent applications are assignable under § 261, but cautioning that inventorship is merely a starting point for determining patent ownership and that the inventor may be subject to an effective transfer of patent rights). Section 261 presumes that the patent holder is the owner. In other words, if the patent holder is not the owner, there can be no assignment; and any document, even though it may have satisfied the requirements of § 261, can not assign the ownership rights. Otherwise, an assignment of a patent by a non-owner could divest the owner of ownership.

Again, we emphasize the critical distinction between vesting of and transferring ownership rights. Vesting by law occurs at conception. Transfer takes place after conception, after ownership has vested. The Florida regulation does not require an employee to transfer his ownership of an invention. It effectively declares that the employee does not own the invention in the first instance.

AIA also argues that the recording of an assignment with the PTO creates a presumption of validity as to the assignment pursuant to 35 U.S.C. § 282. See *SiRF Tech., Inc. v. Int'l Trade Comm'n*, 601 F.3d 1319, 1327-28 (Fed. Cir. 2010) (“[W]e think that [the recording of an assignment with the PTO] creates a presumption of validity as to the assignment and places the burden to rebut such a showing on the one challenging the assignment.”). However, the *SiRF Tech* court cautions that “[t]he recording of an assignment with the PTO is not a determination as to the validity of the assignment.” *Id.* This is consistent with Federal Circuit precedent holding that the presumption of validity is merely a procedural device assigning the burden of proof. See, e.g., *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 780 (Fed. Cir. 1983) (“The presumption is, like all

presumptions in law, a starting place and a procedural device assigning the burden of proof. To treat the presumption as irrebuttable would be to oust the courts of their jurisdiction to consider a challenge to the validity of patents before them.”).

In any event, we do not reach the validity of the assignment unless the assignor’s ownership of the patent is established. If Mullan did not own a valid patent, he had nothing to assign. Only if he legitimately owned a valid patent does § 261 come into play. Holding a properly recorded assignment meeting the § 261 requirements does not *a fortiori* establish ownership of the patent.

AIA relies on a recent Supreme Court case for the principle that where the ownership of an invention is transferred from the inventor by operation of law, the inventor’s rights are not automatically voided unless there is unambiguous language effectuating an automatic transfer of rights. *See Bd. of Trustees of the Leland Stanford Jr. Univ. v. Roche Molecular Sys., Inc.*, No. 09-1159, ___ U.S. ___, 2011 WL 2175210, at *4 (June 6, 2011), *aff’g* 583 F.3d 832 (Fed. Cir. 2009). There, the Court found that the Bayh-Dole Act of 1980, 35 U.S.C. §§ 201(c), (e), 202(a), which allocates rights in federally funded inventions between federal contractors and the government, did not contain unambiguous vesting language. *Id.* at *7. Rather, the Act merely gives contractors an option to retain rights to their work. *Id.*

The *Roche* Court held that the Bayh-Dole Act did not “automatically vest” title to federally funded inventions in federal contractors. It concluded that the Act does not disturb the centuries old principle that the rights to an invention belong to the inventor. *Id.* at *4.

Here, the Florida regulation, unlike the Bayh-Dole Act, unambiguously vests

ownership of its employees' inventions in the University. It states: "An invention which is made in the field or discipline in which the employee is employed by the University or by using University support *is the property of the University* and the employee shall share in the proceeds therefrom." R. 6C4-10.012(3)(c) (emphasis added). This unequivocal language is similar to the statutory language that the Supreme Court noted was necessary to divest inventors of their inventions conceived during work on specified federal contracts. *Roche*, 2011 WL 2175210, at *7. It was the absence of such clear language in the Bayh-Dole Act that made the difference in the case.

Roche does not hold that ownership rights in an employee's invention cannot vest in an employer by operation of law. On the contrary, it acknowledges that it can. However, if a law is intended to vest ownership rights of inventions automatically in the employer, the vesting language must be clearly expressed and unambiguous. *Id.* Thus, *Roche* undermines, rather than supports, AIA's argument.

AIA argues that Mullan was not bound by the Florida regulation because he did not agree to accept its terms. It points out that Mullan did not sign an agreement to be bound by the regulation. Notwithstanding this undisputed fact, Mullan's agreement was not required.

It does not matter that the regulation itself provides that both the University and the employee "shall sign an agreement individually recognizing the terms of this rule." R. 6C4-10.012(4). Nothing in the regulation makes such a written acknowledgment a prerequisite to its enforceability. Said differently, the regulation does not condition its applicability upon execution of such an agreement. In fact, the version of the regulation in force at the relevant time made the regulation applicable by virtue of employment at USF. R. 6C4-

10.001 (Rev. 1/92) (stating that Chapter 6C4 has “university-wide application”).²⁵ When a term in a regulation amounts to a mere formality, the term is not a condition of applicability. See *FilmTec*, 982 F.2d at 1553. Because the requirement of a written document does not affect the applicability of the regulation, the failure to expressly acknowledge the law does not permit an employee to confiscate the employer’s property.

AIA also claims that the regulation was not implemented before the inventions were conceived. It argues that the regulation was not self-executing. Subsection 5 of the regulation states, “The authority and responsibility for administration and implementation of the rule is delegated to the Vice President for Research.” R. 6C4-10.012(5). As Avid correctly contends, the purpose of the provision is simply to identify the official responsible for administering and implementing the regulation. The vesting of property rights in USF took effect when the regulation became effective. It was not postponed until further action was taken. In fact, USF Policy 0-300, which requires completion of a specific disclosure form, tends to contradict AIA’s assertion that the regulation was not implemented. See USF Policy 0-300(IV)(B) (“The disclosure is made by completing and submitting the Disclosure of Invention Form.”)²⁶ Thus, Mullan was bound by the terms of the regulation.

Here, whether Mullan was the sole inventor or a co-inventor, the undisputed facts establish that ownership of the inventions vested in USF by operation of law. There is no dispute that Mullan was employed by USF at the time the inventions were conceived and that the inventions were in the field or discipline of his employment. Thus, because the

²⁵ The provision for university-wide application was in force when the inventions were conceived, but it was repealed in 2003.

²⁶ USF Policy 0-300, “Inventions and Works” (2009), available at <http://generalcounsel.usf.edu/policies-and-procedures/pdfs/policy-0-300.pdf> (last visited August 31, 2011).

Florida regulation vested ownership of the patents in suit in USF, Mullan had no rights to assign to AIA, unless USF had waived its ownership rights.

To summarize, a plaintiff in a patent infringement action must have enforceable title to an invention in order to sue for patent infringement. Under Florida regulations, inventions made by University employees in the course of employment are property of the University. The regulation is binding on employees as a condition of employment, and no written agreement to be bound is required. When an inventor's rights to an invention are transferred by operation of law, the inventor has no rights to assign, and any assignee lacks standing to sue for patent infringement.

Having concluded that the undisputed facts establish that USF had ownership of the invention by operation of law, we must consider AIA's alternative argument that USF waived its interest in the invention. If the waiver was effective and Mullan was the sole inventor, his assignment to AIA was valid. Conversely, if he was the sole inventor but the waiver was ineffective, Mullan had no rights to assign.

Avid argues that when Mullan sought USF's waiver of rights in the Swedish mutation inventions, he did not make the disclosure required by the regulation. As a result, the purported waiver was not made knowingly. So Avid argues, without an effective waiver, Mullan had no rights in the invention to assign to AIA.

Under the Florida regulation, USF employees are under a duty to disclose to USF any inventions made during the course of their employment. R. 6C4-10.012(3)(a). The regulation also contains a waiver provision, which provides that the University may elect to transfer its rights to employees' inventions at the request of the employee. To be effective, any assignment or release of rights must contain a provision that the invention

remains available royalty-free to the State of Florida for governmental purposes. R. 6C4-10.012(3)(e)(2)-(3). This provision assures that Florida retains an interest in the invention.

The purported waiver letter relied upon by AIA sought a waiver of rights of inventions of Mullan and Hardy.²⁷ It makes no mention of the Swedish mutation invention. While denying that Mullan was under such an obligation, AIA apparently does not dispute that Mullan never specifically disclosed the Swedish mutation invention to USF prior to the waiver letter.²⁸ This omission, Avid argues, constitutes a failure to disclose the invention as required by the regulation. Furthermore, USF Policy 0-300 requires completion of a specific disclosure form. See USF Policy 0-300(IV)(B) ("The disclosure is made by completing and submitting the Disclosure of Invention Form."). There is no evidence that Mullan ever completed such a form. He did not fulfill his disclosure obligation. Without Mullan's disclosure of the Swedish mutation invention, a question arises whether USF's purported waiver could have been knowing.

What Mullan, Hardy and USF understood and intended by the letter countersigned by Newkome, USF's Vice-President for Research, is not clear. The letter is susceptible to more than one meaning. A fact finder could reasonably infer that the letter was an agreement to agree at a later time how the rights to any inventions would be treated. It reads, "... to avoid any further arguments about ownership or rights to exploit which might impede exploitation, until formal arrangements for exploitation, in which our Clients [Hardy and Mullan] would like USF to be involved, have been settled." In the next paragraph, the

²⁷ The fact that Mullan and Hardy jointly sought a waiver tends to show that they were co-inventors. Because there are disputed material facts on the inventorship issue, we cannot decide whether the Swedish mutation was jointly created by Mullan and Hardy or by Mullan alone.

²⁸ At oral argument, AIA's counsel suggested that USF had to have known about the Swedish mutation discovery because it appeared in scientific literature.

attorneys wrote that the clients wanted confirmation that they had ownership rights in any inventions “until specific formal arrangements for exploitation and ownership have been agreed.” It could be, as AIA argues, a relinquishment of USF’s rights to any and all inventions. Or, it could be an acknowledgment of USF’s rights and a recognition that any benefits from those rights were to be negotiated later. These inferences are for the jury to draw.

Conclusion

There are disputed material facts regarding whether Mullan was the sole inventor of the Swedish mutation. If he was the sole inventor, as a matter of law, ownership rights to the invention vested in USF by operation of law. There are contested material facts relating to whether USF waived its ownership rights. Therefore, the cross-motions for summary judgment will be denied.

This case will proceed to trial to determine whether AIA, as Mullan’s purported assignee, has standing. A jury must determine whether Mullan was the sole inventor; and, then if it decides he was, whether USF waived its legal ownership rights in the invention.